FACILITY AUTOMATION MANAGEMENT ENGINEERING SYSTEMS
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Tuesday, 30 December 2003

Documents Management Branch [**HFA-305**]
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 03D-0380

FORMAL COMMENTS ON:

"**Draft Guidance for Industry on PAT—A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance** "

Pursuant to a "request for comment" in ***FEDERAL REGISTER*, Vol. 68**, **No. 172**, pp 52781 – 52782.

The following document is a revised draft of the Draft published by the Agency for review and comment.

This revised Draft is based on the submitter's review of the original draft and all comments available electronically in this Public Docket that were published therein in September, October and November of 2003.

In support of this revised Draft, the submitter is separately submitting the comments made and the submitter's in-depth review thereof.

Except for quotations from Federal statutes and regulations, the revised Draft is set in a "Times New Roman" font

The quoted references in Federal documents are presented in a "Lydian" font.

Except for deletions, the changes in the body of the Draft are highlighted in red.

Should anyone in the Agency who reviews this revised Draft need clarification on a given text passage beyond that provided in the supporting document, then, they should e-mail drking@dr-king.com the passage in question along with his or her salient question or questions appertaining thereto.

Hopefully, this submission will expedite the Agency's issuance of a guidance or PAT that fully meshes with the statutes and regulations governing the industry and provides a scientifically sound framework upon which the industry can build its submission documents for drug production processes, within the scope of this guidance, that use one or more PAT-based controls in the manufacture of a drug (component, intermediate, drug substance, or finished pharmaceutical).

Respectfully,

Dr. King